

Data Evaluation Report on the effects of saflufenacil on carbon transformation

PMRA Submission Number: 2008-0430

MRID#: 474308-01

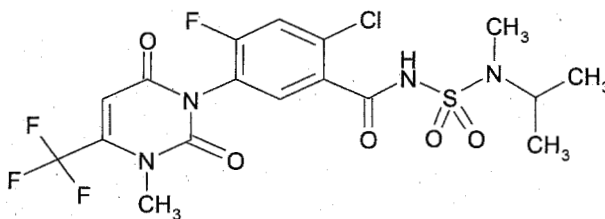
PMRA# for DER: 1604187

PMRA# for original study: 1599145

Data requirement EP
 PMRA Data Code: 9.9
 EPA DP Barcode: 349851
 OECD Data Point: IIIA 10.7.2
 EPA Guideline: n/a
 OPPTS Guideline: n/a

Test material: BAS 800 01 H **Guarantee:** 70.0% BAS 800 H

Active ingredient: saflufenacil
IUPAC: N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide
CAS name: 2-chloro-5[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluoro-N-[(methyl(1-methylethyl)amino)sulfonyl]-benzamide
CAS No.: 372137-35-4
Synonyms: BAS 800 H
Structural formula:



Primary Reviewer: Janine Glaser (1009)
 Canada-HC-PMRA-EAD

Date: 2008-Aug-7

Secondary Reviewers: Anita Pease
 United States-EPA-OPP-EFED-ERB4

Date: 2009-Jun-09

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Date: 2008-Dec-17

PMRA Company Code BAZ

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PMRA Active Code SFF
PMRA Use Site Category 13, 14
EPA PC Code 118203

CITATION: Schulz L. 2008. Effects of BAS 800 01 H on the activity of soil microflora (carbon transformation test). 2008-Apr-24. BASF-2008/1010677; MRID-474308-01; PMRA-1599145.

EXECUTIVE SUMMARY

In a soil microbial activity study, the effects of the formulated product BAS 800 01 H on carbon transformation were investigated in a loamy sand soil. BAS 800 01 H was applied to samples of the soil at nominal test concentrations of 0.93 and 9.33 mg product/kg dry soil (0.65 and 6.53 mg a.i./kg dry soil), equivalent to 0.70 and 7.0 kg product/ha (0.49 and 4.9 kg a.i./ha) for a 5-cm soil depth, or 2.1 and 21.0 kg product/ha (0.15 and 14.7 kg a.i./ha) for a 15-cm soil depth. BAS 800 01 H treated soils and controls were incubated at approx. 20°C in the dark. Triplicate samples of each treatment were removed for analysis of oxygen consumption 0, 7, 14, and 28 days after application. Deviations from control were 0.2-1.3% stimulation in the 0.93 mg product/kg dry soil treatment and 1.7% inhibition to 1.7% stimulation in the 9.33 mg product/kg dry soil treatments. Therefore, there were no significant effects (i.e., deviations from controls were <25%) on carbon transformation at any application rate at any time period up to 28 days of incubation.

This study is classified as **FULLY RELIABLE** to PMRA and APVMA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment.

Results Synopsis

Process:	carbon transformation
Test duration:	28 days
Endpoint:	oxygen consumption
Soil concentration:	0.93 and 9.33 mg product/kg dry soil (0.65 and 6.53 mg a.i./kg dry soil)
Deviation from control:	0.2-1.3% stimulation and 1.7% inhibition to 1.7% stimulation

I. MATERIALS AND METHODS

Guideline: OECD 217
GLP: yes (certified laboratory)
Testing facility: BioChem agrar, Labor Für biologische und chemische Analytik GmbH, Gerichshain, Germany
Dates of work: 2008-Mar-19 to 2008-Apr-24
Deviations: none

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A. Test substance

Name: BAS 800 01 H
Type of formulation: WG (water dispersible granules) formulation
Batch No.: 1641-87
Expiry date: 2009 Sep 12
Content: 68.8% saflufenacil (analysed)

Table 1: Physical and chemical properties of active substance

Parameter	Value
Water solubility	pH 4 0.0014 g/100 mL
	pH 5 0.0025 g/100 mL
	pH 7 0.21 g/100 mL
	pH 9 not determined due to degradation
Vapour pressure	4.5×10^{-13} Pa at 20°C
	2.0×10^{-14} Pa at 25°C
UV absorption	pH 1.12 6.94
	λ_{\max} (nm) 271.8 271.4
	ϵ (L/mol-cm) 9539 9708
pK _a	4.41
log K _{ow}	2.6

B. Test solutions

Test item mixed with: deionised water
Method of preparation: 200 g sieved soil (2 mm) was treated with 7.20 mL stock solutions (deionized water)

C. Test soil

Soil nomenclature : loamy sand
Collection depth : 20 cm
Batch no.: 1/2008
Source: Schlag 34/2, Wassergut Canitz, Saxony, Germany
Date of collection: 2008 Feb 8
Storage temperature: approx. 4°C
Storage duration: <2 months

Particle size distribution (% w/w):
Sand (2-0.063 mm): 50.6
Silt (0.063-0.002 mm): 39.5
Clay (<0.002 mm): 9.8

Soil properties:

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% organic carbon:	1.43
biomass (mg microbial C/100 g dry soil):	30.56
% microbial C of organic carbon:	2.14
% nitrogen:	0.13
pH:	6.7
Cation exchange capacity (cmol ⁺ /kg soil):	9.5

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History of soil:

Pest control products not used since: 1990

Fertilisers not used since: 2003

Crops: fallow ground

D. Design of biological test

Rates of 0.93 and 9.33 mg product/kg dry soil (0.65 and 6.53 mg a.i./kg dry soil, respectively) were applied on the soil, corresponding to 0.70 and 7.0 kg product/ha (0.49 and 4.9 kg a.i./ha) for a 5-cm soil depth, or 2.1 and 21.0 kg product/ha (0.15 and 14.7 kg a.i./ha) for a 15-cm soil depth. In addition, an untreated soil control was tested. Each vessel (4 L steel vessel) served as one replicate filled with 1200 g dry soil for each treatment level. The test was conducted with 3 replicates per treatment level. The test was conducted at 19.7-21.0°C in the dark.

D. Observation and measurements

At day 0 (3 hours), and after 7, 14, and 28 days of incubation, subsamples (moist samples equivalent to 100 g dry soil) were taken from each flask and amended with 0.4% glucose. The oxygen consumption was measured over a period of 12 hours using a "BSB-digi" respirometer system. The water content of the soil in each test vessel was determined at test start (after application) and adjusted once a week to the required range of 40-50% of WHC. The pH values were measured at test start (after application) and on day 28.

II. RESULTS

A. Physical and chemical parameters

The soil pH was 6.6-6.7 at test start and 6.5 after 28 days in all treatment groups. The water content was 16.18-16.87 g/100 g dry soil (equivalent to 42.73-44.55% of water holding capacity).

B. Biological findings

The deviation from the control did not exceed 25% after 28 days (Table 2).

Table 2: Effects of BAS 800 01 H on carbon transformation in loamy sand soil given as deviation from control

	Control	0.93 mg product/kg dry soil (0.65 mg a.i./kg dry soil)		9.33 mg product/kg dry soil (6.53 mg a.i./kg dry soil)	
Day	mg O ₂ / kg dry soil/hour	mg O ₂ / kg dry soil/hour	% deviation from control	mg O ₂ / kg dry soil/hour	% deviation from control
0	11.87	12.03	+1.3	12.07	+1.7
7	10.93	10.96	+0.2	10.75	-1.7
14	11.30	11.33	+0.3	11.25	-0.5
28	9.95	10.01	+0.6	9.96	+0.1

- = inhibition; + = stimulation

C. Validity criteria

The coefficients of variation in the control (oxygen consumption) were maximum 1.1% and thus fulfilled the demanded range ($\leq 15\%$) (Table 3).

Table 3: Variation in control replicates on NO₃-N in loamy sand soil given as % coefficient of variation

	Day 0	Day 7	Day 14	Day 28
% c.v.	0.3	0.1	0.7	1.1

D. Test with toxic reference substance

The reference item was dinoterb (purity $98.0 \pm 0.5\%$). The reference item was tested in a separate study (2008 Jan 29 to Feb 26). Dinoterb caused 24.8%, 42.0% and 49.0% inhibition (required $\geq 25\%$) of carbon transformation at the tested concentrations of 6.80, 16.00, and 27.00 mg/kg dry soil, respectively, 28 days after application. Thus, the test with toxic reference substance demonstrates the sensitivity of the test system.

III. STUDY DEFICIENCIES

None.

V. CONCLUSIONS

This study is classified as **FULLY RELIABLE** to PMRA and APVMA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment. BAS 800 01 H has negligible effects on carbon transformation by soil microflora up to 9.33 mg product/kg dry soil (6.53 mg a.i./kg dry soil), which corresponds to 7.0 kg product/ha (4.9 kg a.i./ha) for a 5-cm soil depth, or 21.0 kg product/ha (14.7 kg a.i./ha) for a 15-cm soil depth.